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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/17/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/501,328

Applicant(s)

MACKLIN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20May2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,10,11,13-16,18,19,21-30,32,33,35-42,44,45 and 47-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 50-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,10,11,13-16,18,19,21-30,32,33,35-42,44,45 and 47-49 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-8,10,11,13-16,18,19,21-30,32,33,35-42,44,45 and 47-55.

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DETAILED ACTION

1. Applicants' Response to Office Action, received 20May2002, paper#13, is acknowledged.

Claims 9, 12, 17, 20, 31, 34, 43, and 46 have been canceled without prejudice.

Claims 7, 10, 11, 13, 15, 18, 19, 21, 25, 26, 32, 33, 35, 37, 44, 45, and 47 have been amended.

2. Claims 1-8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-55 are pending. Claims 1-6 and 50-55 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) as being drawn to a nonelected invention.

3. Claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 are under consideration.

Rejections/Objections Moot/Withdrawn

4. The objection to claims 9, 12, 17, 20, 31, 34, 43, and 46 because the claims depend from nonelected claims is moot in light of the cancelation of the claims.

5. The rejection of claims 9, 12, 17, 20, 31, 34, 43, and 46 under 35 U.S.C. 112, second paragraph, indefiniteness, for "secondary composition", is moot in light of the cancelation of the claims.

6. The rejection of claims 43 and 46 under 35 U.S.C. 112, second paragraph, lack of antecedent basis, is moot in light of the cancelation of the claims.

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7. The rejection of claims 9, 12, 17, 20, 31, 34, 43, and 46 under 35 U.S.C. 112, first paragraph, scope of enablement for any and all other combinations of *M. tuberculosis* antigens, is moot in light of the cancelation of the claims.

8. The rejection of claims 9, 12, 17, 20, 31, 34, 43, and 46 under 35 U.S.C. 112, first paragraph, scope of enablement for eliciting an immune response as defined in the specification, is moot in light of the cancelation of the claims.

9. The rejection of claims 9, 12, 17, 20, 31, 34, 43, and 46 under 35 U.S.C. 112, first paragraph, scope of enablement for eliciting an immune response in humans, is moot in light of the cancelation of the claims.

10. The rejection of claims 9, 12, 17, 20, 31, 34, 43, and 46 under 35 U.S.C. 112, first paragraph, scope of enablement for boosting steps using secondary compositions, is moot in light of the cancelation of the claims.

11. The rejection of claims 9 and 17 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997), is moot in light of the cancelation of the claims.

12. The rejection of claims 31 and 43 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997) in view of Sanford et al (U.S. Pat. No. 5,100,792), is moot in light of the cancelation of the claims.

13. The objection to claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 because the claims depend from nonelected claims is withdrawn in light of the claim amendments.

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14. The rejection of claims 37-42, 44, 45, and 47-49 under 35 U.S.C. 112, second paragraph, lack of antecedent basis, is withdrawn in light of the claim amendments.

15. The rejection of claims 13, 14, 21, 22, 35, 36, 47, and 48 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendments.

16. The rejection of claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 under 35 U.S.C. 112, first paragraph, scope of enablement for any and all other combinations of *M. tuberculosis* antigens, is withdrawn.

17. The rejection of claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 under 35 U.S.C. 112, first paragraph, scope of enablement for eliciting an immune response as defined in the specification, is withdrawn.

Rejections/Objections Maintained

18. The objection to claim 26 for an informality is maintained. While the original objection was corrected. The new form of the claim has a “[” immediately prior to “the core”.

19. The rejection of claims 8, 16, 30, and 42 under 35 U.S.C. 112, second paragraph, indefiniteness, for “secondary composition”, is maintained for reasons set forth in the original rejection.

Applicants argue that the use of “secondary composition” is clear from a proper reading of the specification and accompanying working examples.

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The examiner has considered applicants' argument, but does not find it persuasive.

While the specification may teach certain embodiments, the claims remain indefinite because the "secondary composition" is not defined.

20. The rejection of claims 7, 8, 10, 11, 13-16, 18, 19, 21-30, 32, 33, 35-42, 44, 45, and 47-49 under 35 U.S.C. 112, first paragraph, scope of enablement for eliciting an immune response in humans, is maintained.

Applicants argue that the guinea pig model is a well established model in the field of *M. tuberculosis*, and that studies of events in infected humans who follow similar patterns. In addition, applicants argue that the rejection is an improper requirement that applicants must have actually carried out human studies.

The examiner has considered applicants' arguments, but does not find them persuasive. The teachings of the specification must be sufficiently enabled for one skilled in the art to accomplish the claimed invention. The field of tuberculosis is a unique example in animal/human studies in that the use of animal models to predict success in humans has been universally unsuccessful except for the one example, BCG. Thus, enablement of the instant claims is not an improper requirement that applicants must have actually carried out human studies, but that the prior art provide the necessary enablement in the absence of such enablement in the instant specification, i.e., animal models predict success in humans. Because the prior art teach that, to date, there have been no successful human studies even though guinea pig studies

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appear to be successful, the enablement requirements do fall on the instant specification for the necessary support.

21. The rejection of claims 8, 10, 11, 13, 16, 18, 19, 21, 30, 32, 33, 35, 42, 44, 45, and 47 under 35 U.S.C. 112, first paragraph, scope of enablement for boosting steps using secondary compositions, is maintained for reasons set forth in the original rejection.

Applicants argue that the instant specification does enable the instant claims and that the examiner has provided no basis for why the composition would not be predictive from the teachings of the specification.

The examiner has considered applicants' argument, but does not find it persuasive.

Claims 8, 16, 30, and 42 read on the secondary composition being of any unknown/unrestricted source, with no requirement that it comprise any of the initial *M. tuberculosis* antigens. Thus, it is unknown how one boosts the response to *M. tuberculosis* antigens with, e.g., secondary composition of cancer cells or viral proteins.

Claims 10, 11, 18, 19, 32, 33, 44, and 45 read on the secondary composition being of any antigens of *M. tuberculosis*, with no requirement that it comprise any of the initial *M. tuberculosis* antigens. Thus, it is unknown how one boosts the response to one set of *M. tuberculosis* antigens with a secondary composition of totally different *M. tuberculosis* antigens.

Claims 13, 21, 35, and 47 reads on the secondary composition being of any species of *Mycobacterium*. However, the instant specification provides no guidance on what other species

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of *Mycobacterium*, other than BCG, contains the necessary epitopes for boosting an immune response to *M. tuberculosis*.

22. The rejection of claims 7, 8, 10, 11, 15, 16, 18, and 19 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997), is maintained for reasons set forth in the original rejection.

Applicants argue that while Lowrie et al do teach a number of discrete mycobacterial antigens as DNA vaccines, they neither taught or suggested combining two or more antigens in their study.

The examiner has considered applicants' argument, but does not find it persuasive. The motivation to produce a combination of antigens is suggested by the cited passage in Lowrie et al. The statement is directed to "a" vaccine with "endogenous expression of only a few proteins".

23. The rejection of claims 23, 25-30, 32, 33, 37-42, 44, and 45 under 35 U.S.C. 103(a) as being unpatentable over Lowrie et al (*Vaccine*, 15(8):834-838, 1997) in view of Sanford et al (U.S. Pat. No. 5,100,792), is maintained for reasons set forth in the original rejection.

Applicants argue that while Lowrie et al do teach a number of discrete mycobacterial antigens as DNA vaccines, they neither taught or suggested combining two or more antigens in their study. Applicants argue that Sanford et al does not provide the missing teaching or suggestion.

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The examiner has considered applicants' argument, but does not find it persuasive. The motivation to produce a combination of antigens is suggested by the cited passage in Lowrie et al. The statement is directed to "a" vaccine with "endogenous expression of only a few proteins".

Sanford et al is cited to teach transdermal delivery systems utilizing a core carrier.

Conclusion

24. No claims are allowed.

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
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July 15, 2002